

4. (Original) The composition of claim 3, wherein the microgel has a ratio of the macroviscosity of the microgel to the microviscosity of the microgel is 10,000 or less.

5. (Original) The composition of claim 1, wherein the polyanionic polymer is functionalized to provide one or more pendant functional groups selected from hydroxy, acyl halide, chloroformate, and mercapto; and wherein the linking moiety provides crosslinking and is a reaction product of the pendant groups between polymer segments or between the pendant groups and complementing functions groups of a linking group.

6. (Original) The composition of claim 5, wherein the linking agent is the diacrylate of an α,ω -diol or the diacrylate of a chain extended α,ω -diol.

7. Previously cancelled.

REMARKS

After amendment, claims 1-6 remain pending in the present application. Claim 7 was previously cancelled canceled in the response to the Restriction Requirement of January 7, 2003. No amendment has been made to distinguish over the art of record. A review of the present claims in comparison to the disclosures cited against the instant application evidences that the presently claimed compositions are clearly patentable over the disclosures of the cited art. None of the prior art references cited against the instant application disclose or even remotely suggest polymer compositions as they are presently claimed.

The Examiner has rejected claims 1-6 under 35 U.S.C. §102 and §103 as being invalid for the reasons which have been stated in the office action. Applicants will address the Examiner's rejection hereinbelow.

The §102/103 Rejection Based Upon the Cited Art

The Examiner has continued to reject claims 1-6 under 35 U.S.C. §102(b) as being anticipated by, or in the alternative, under 35 U.S.C. §103(a) as being obvious over Roth, et al., U.S. patent no. 5,999,475 ("Roth"), Kawai, et al., U.S. patent no. 5,302,312 ("Kawai") or Williams, et al., British patent application GB 2,215,335 ("Williams") for the reasons which were stated in the previous office action on pages 2-3. Essentially, it is the Examiner's position that each of the above three references teach the claimed microgels made from acrylic acid monomers and containing the potential "anionic" entities as well as the cross-linking required by applicants' claims. The Examiner notes that the references are silent with respect to the specific properties of the microgels required, but he presumes them to have the same properties as the claimed microgels absent evidence to the contrary. Applicants respectfully traverse the Examiner's rejection.

The Present Invention is Clearly Distinguishable Over the Art of Record

As set forth hereinabove, the present invention relates to novel compositions comprising a pre-formed hydrolytically susceptible non-addition polyanionic polymer which comprises polymer strands linked by at least one linking moiety comprising a hydrolytically susceptible bond formed with a multidentate compound comprising two or more ethylenically unsaturated moieties, each such moiety being linked to the multidentate compound through a hydrolytically susceptible bond wherein the at least one of the monomers has at least one of functional groups or precursors of those functional groups which can be converted to the functional groups, the ethylenically unsaturated monomers according to the composition being described according to the formula set forth in claim 1. Applicants respectfully submit that the claimed compositions, which represent novel compositions for use in medical treatments or other applications as described in the specification, are novel and patentable over the cited art references.

Noted here is the fact that the instant compositions, by virtue of their having hydrolytically susceptible moieties which link *both* the polymer strands to the multidentate

compound and the multidentate compound to at least two or more ethylenically unsaturated moieties, these compounds are clearly distinguishable over the cited art. By virtue of this dual hydrolytic susceptibility, polymers as presently claimed are very sensitive to hydrolytic degradation. This characteristic, incorporated into the chemical structure of the claimed polymer, is particularly useful for presentation of the polymer in medical devices and suited for delivery into the human body, where the increased hydrolytic susceptibility of the polymers will ultimately aid in their hydrolytic degradation and bioresorbability (i.e., these polymers will eventually be removed from the body of the patient as they hydrolytically break down to smaller units and pass out of the body). The characteristics of the presently claimed polymers as embodied in the claimed chemistry is neither disclosed nor suggested by the art of record. Indeed, a review of the art shows that its teachings are *inapposite* to the present invention or may actually *teach away* from the present invention. None of the cited references, either alone or in combination teach or suggest the instant invention.

Roth does not disclose or suggest the present invention. Roth is directed to reaction products of an amine and a carboxyl function microgel which are to be used in epoxy resin systems. The Roth compositions contain amines (nitrogen-containing bases) as hardeners or as curing accelerators for the epoxy resins. The compositions disclosed in Roth do not anticipate the present invention, in the first instance, because the amine-containing accelerators of Roth (those compositions of Roth most relevant to the present invention) do not disclose or suggest the present invention and the combination of the amine-containing accelerators and the epoxy resin combinations are clearly not the present invention. No cogent argument can be made that Roth somehow anticipates the presently claimed compositions. Roth clearly does not suggest the present invention because the present invention is directed to enhancing hydrolytical susceptibility by virtue of the polymer structure, whereas Roth is directed to polymers which are used as epoxy resins, such resins containing such additional additives as metal powder, wood dust, glass powder, etc. It is quite clear that the Roth polymers are designed for enhancing stability, the exact opposite of the present invention. Thus, it can be forcefully argued that Roth in this regard actually *teaches away* from the present invention by virtue of teaching polymers of enhanced stability, not those, like the present invention which teach increased *susceptibility* to

hydrolysis as a desirable feature. Thus, a review of Roth shows that the teachings of Roth do not make out the compositions according to the present invention, nor can they possibly suggest the present invention for the reasons stated.

Turning to Kawai, this reference does not disclose or suggest the present invention. Kawai is directed to a detergent for contact lens compounds which are designed for two purposes. The first is to increase the osmotic pressure caused by dissolving fine particles of water-soluble compounds into water at the time of washing a contact lens and the second is to reduce and/or eliminate dehydration of a contact lens caused by a disperse medium to suspend fine particles of water-soluble compounds and interaction of the disperse medium and the lens (see column 2 of Kawai). It is apparent from the disclosure of Kawai that Kawai does not disclose the polymeric compositions which are claimed in the instant invention because no polymer disclosed in Kawai meets the limitations of claim 1 of the instant invention. Moreover, the polymers of Kawai are not particularly susceptible to hydrolysis because this would essentially defeat the purpose of having a detergent. Regarding the question of obviousness, the compositions of Kawai, useful in formulating detergents for cleaning contact lenses clearly do not suggest the present compositions which find use in medical applications. Moreover, there is no motivation to adapt the teachings of Kawai to those of the instant invention inasmuch as Kawai does not suggest the use of the compositions in medical applications, but rather as surfactants to clean contact lenses, a clearly distinguishable use. Kawai teaches away from the present invention inasmuch as Kawai *requires* that the detergents be stable for their use in solution, whereas the present polymers exhibit enhanced *susceptibility* to hydrolysis- a characteristic clearly distinguishable from the teachings of Kawai. Thus, Kawai also *teaches away* from the present invention inasmuch as the Kawai polymers must be stable and useful in solution whereas the present compositions are hydrolytically susceptible in solution. There can be no motivation from Kawai to make the instant polymers because the desired characteristic of the Kawai polymers is the detergent action in solution. One of ordinary skill would not seek to modify the Kawai polymers to make the instant invention inasmuch as doing so would defeat the very purpose Kawai made his polymers- for use as detergents in solution. It is respectfully submitted that Kawai does not in any way render the present invention unpatentable.

Turning to Williams, it is respectfully submitted that this reference does not disclose or suggest the present invention. Williams is directed to immobilized enzyme conjugates which are soluble or dispersible in an organic solvent-containing medium prepared from a polymer microgel which contains significant hydrophobic groups, the polymer being conjugated via covalent linkages with the enzyme. A review of the chemistry of Williams with that of the claimed invention evidences that the present invention and the disclosed chemistry of Williams are not the same- Williams cannot therefore be construed as an invalidating (anticipating) reference. Williams clearly does not disclose or suggest a polymer structure such as the instant invention which *advantageously* enhances susceptibility to hydrolysis. Indeed, the Williams compositions are directed to the conjugation of hydrophobic microgels and enzymes to enhance the reactivity of the enzyme in a non-aqueous solvent (methanol or tetrahydrofuran). Thus, Williams clearly does not anticipate the presently claimed compositions. Regarding the question of obviousness, Williams cannot be an invalidating reference, inasmuch as it teaches a polymer to facilitate enzymatic reactions in organic solvents, an approach which is in apposite to the present invention and its direction of rendering polymeric compositions useful in medical applications through the hydrolytic susceptibility of its polymer structure. In short, Williams does nothing to invalidate the present invention or cure the clear deficiencies of the other cited art in failing to invalidate the present invention.

In sum, no cited reference or combination of references discloses or even remotely suggests the use of hydrolytically susceptible polymeric compositions according to the present invention. Looking at the cited references in combination, there is simply no teaching of any one of the references or the combined references that it is advantageous to produce a hydrolytically susceptible polymer according to the present invention. If anything, the combined references are inapposite or actually *teach away* from the present invention. Thus the present invention is neither disclosed in the art nor are the advantages or desirability of such an invention even remotely suggested in the art. This is sufficient proof of the patentability of a claimed invention. Consequently, it is respectfully submitted that the instant application is patentable.

It is respectfully submitted that the claimed invention is in compliance with the requirements of 35 U.S.C. For the above reasons, Applicant respectfully asserts that the claims set forth in the amendment to the application of the present invention are now in condition for allowance and such action is earnestly solicited.

Applicant has neither added nor cancelled any claim. No fee is due for the presentation of this amendment. Small entity applies to the present application. A one month extension of time is enclosed as is a notice of appeal and authorization to charge Deposit Account 04-0838 in the amount of \$220.00. A revocation of power of attorney and appointment of substitute counsel was previously submitted. If the Examiner wishes to discuss the instant amendment in an effort to discuss the allowability of the instant invention, he is cordially invited to call the undersigned at the telephone number indicated below.

Respectfully submitted,

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I hereby certify that this correspondence is being sent by facsimile transmission to Examiner Bernard Lipman in Art Unit 1713 of the United States Patent and Trademark Office on March 18, 2004.


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